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Wisconsin Healthcare Engineering Association

December 7, 2004

Dockets Management Branch (HFA-305)
Food & Drug Administration
Mr. Daniel G. Schultz, M.D. Director
Center for Devices in Radiological Health:
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket # 2004D-0343

Dear Dr. Schulz:

This letter is submitted on behalf of the Wisconsin Healthcare Engineers Association regarding the draft guidance document entitled "Hospital Bed System Dimensional Guidance to Reduce Entrapment" as published in the Federal Register of August 30, 2004 (69 FR 52907).

In a letter to Janet Trunzo, you indicated that comments submitted in this format will be considered in preparation of a final guidance. The Wisconsin Healthcare Engineers Association Codes & Standards Committee reviewed and discussed the document at the December 2nd meeting. The Wisconsin Healthcare Engineers Association fully supports creating a safer environment for our patients accessing services in healthcare in the United States.

The Wisconsin Healthcare Engineers Association, however, would like to strongly encourage the FDA to eliminate the sections of the document that make it retroactive in any manner. At the current time, the Wisconsin Healthcare Engineers Association is not aware of any product or bed system manufactured prior to this year that met the standards of this draft guidance.

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If the retroactivity requirements of this document are not removed, healthcare will be forced to:

- a. Incur additional responsibility and liability if anyone were to be injured in any existing beds, or
- b. replace all the existing beds throughout the country in nursing homes and hospitals with a new bed.

The financial capital required to complete this would be unbearable to the national healthcare system. The frequency of occurrences do not justify the extensive capital outlay required for all healthcare to accomplish this compliance with this document immediately as discussed in the draft guidance document. This additional requirement is unnecessary as well as inappropriate. The new guidance should be adopted for manufacturers and future purchases.

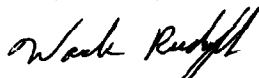
The Wisconsin Healthcare Engineers Association does support improved criteria for manufacturers to eliminate a rare risk that can be eliminated and engineer out of the equation.

The statistical occurrence of bedrail entrapments is extremely rare and forcing healthcare to replace all these beds is a significant capital outlay that, therefore, deny the citizens of the United States other opportunities for improved technique in advanced medical procedures to save lives.

As the Wisconsin Healthcare Engineers Association Code Committee Chair, I represent 400 members throughout the state of Wisconsin. It is the feeling of the Wisconsin Healthcare Engineers Association that more lives would be saved by allowing facilities to use capital dollars to pursue safer and newer treatment methods in leu of replacing the hospital beds in all the facilities across the country.

If you have any questions or concerns, feel free to contact me at 715-848-4486.

Respectfully Submitted,



Wade E. Rudolph
WHEA Codes & Standards Committee Chair

WR:cm

xc: Mr. Wayne Johnson, WHEA President
Director of Facility Operations
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